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APPENDICES

List of Abbreviations

AAHCC	American Accrediation Health Care Commission
AAPI	American Accrediation Program, Inc.
AMHO	Association of Managed Healthcare Organizations
ASO	Administrative services only
BOH	Board of Health
CFR	Code of Federal Regulations
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services
DHES	Department of Health Evaluation Science, University of Virginia
DHP	Department of Health Professions
DMAS	Department of Medical Assistance Services
DOL	Department of Labor, U.S.
EOC	Evidence of Coverage
ERISA	Employee Retirement Income Security Act
HB 2785	House Bill 2785
HCFA	Health Care Financing Administration
HEDIS	Health Plan Employer Data Information Set
HJR 611	House Joint Resolution 611
HMO	Health Maintenance Organization
IOM	Institute of Medicine
JCHC	Joint Commission on Health Care
MOA	Memorandum of Agreement
MCO	Managed care organization
NAIC	National Association of Insurance Commissioners
NCQA	National Committee for Quality Assurance
NGA	National Governors' Association
PCP	Primary care providers
POS	Point of Service
PPO	Preferred provider organization
PRO	Peer Review Organization
QA	Quality Assurance
SIR	Southern Institute of Research, Inc.
SJR 67	Senate Joint Resolution 67
TPA	Third party administrator
UM	Utilization management
UR	Utilization review
URAC	Utilization Review Accrediation Council
UVA	University of Virginia
VDH	Virginia Department of Health
VHI	Virginia Health Information, Inc.

I. EXECUTIVE SUMMARY

Rapid shifts in the health care market have led consumers to demand assurances that the quality of care delivered and the level of protections afforded to them be optimized in Health Maintenance Organizations (HMOs) and other forms of managed care. During the past few years in particular, states have enacted many laws intended to address managed care limits on access to providers and services. However, regardless of the content and scope of new legislation, consumer protections depend on an impartial authority that can validate compliance with the law. The traditional regulation of insurance through the State Corporation Commission's Bureau of Insurance (BOI) was intended to address issues such as licensure, solvency, trade practices, and conduct in the marketplace. HMOs and other forms of managed care provide more than health insurance; they also provide a delivery system for care, and the BOI recognized the necessity for an expanded scope of oversight to address medical and clinical issues. Until very recently the Virginia Department of Health (VDH) has not been active in assuring the quality of care in HMOs, and it has never had authority to conduct quality of care examinations in other forms of managed care organizations (MCOs).

The 1997 General Assembly took a comprehensive approach to quality protections and passed House Bill 2785 (HB 2785, Appendix A), which required that the State Health Commissioner examine the quality of care plans and enrollee complaint systems of HMOs. In addition, it directed the State Health Commissioner to study the quality of health care services delivered in HMOs and other MCOs and recommend the "appropriate role of the Commonwealth in monitoring and improving the quality of care in managed care plans . . . ." The following report reviews and analyzes selected federal and state statutes and regulations governing quality of care and grievance protections for Virginians in managed care plans. While it focuses on HMOs, this report also explores other forms of managed care, such as preferred provider organizations (PPOs).

In an attempt to involve all parties affected by this review, a study group was formed consisting of relevant state agencies,[1] consumers and representatives from the health care industry.[2] The study group addressed several questions. First, what is the current role of the Commonwealth in monitoring and improving the quality of care in HMOs and other forms of managed care? Second, what private sector activities are currently being undertaken to assure high quality of care in HMOs and other forms of managed care? Third, how adequate are the current public and private mechanisms to assure high quality in MCOs? Fourth, should all managed care entities be held accountable for quality of care protections? Fifth, what is the appropriate role of the Commonwealth in monitoring and improving quality of care in managed care organizations?

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[1]Departments of Health Professions, Medical Assistance Services, and Health, and the Bureau of Insurance.

[2]Virginia Hospital and Healthcare Association, Virginia Association of HMOs, Medical Society of Virginia, Virginians for Patient Choice, and Virginia Chamber of Commerce.

More than a dozen separate analyses were undertaken to provide responses to the study questions, involving standard research methods such as statutory analyses, interviews, focus groups, surveys, and selective literature reviews. VDH contracted with the University of Virginia, Department of Health Evaluation Sciences (UVA/DHES) to conduct objective research to supplement the analyses developed by VDH. In particular, UVA reviewed the current quality assurance plans and complaint procedures in managed care plans. UVA also worked with The Southeastern Institute of Research, Inc. (SIR) to conduct a random survey of Virginians to determine consumers' awareness of their rights and responsibilities regarding complaint procedures for their health plan.

The working definition of quality used by the Study Group was adopted from Virginia's health facilities regulatory program. Specifically it derives from the definition contained in the *State Medical Facilities Plan* (12VAC5-230). The scope of the definition applies to seven components of quality recognized by the health care industry as appropriate areas for state oversight during a Round Table on *The Quality of Care in Network-Based Health Delivery Systems* convened by the State Health Commissioner in August 1996. These "consensus" components are: (1) complaint resolution and consumer satisfaction; (2) access and availability; (3) prevention; (4) credentialing; (5) consumer/provider education and awareness; (6) outcome measures and accountability; and (7) improvement of community health. These "consensus" components are the focus for analysis in this report. This review assesses whether the Commonwealth has sufficient authority for monitoring and improving the managed care health plans' policies, procedures, and programs affecting these components of quality. However, there are unresolved issues about the definition and the meaning of the "consensus" components.

Consumers should have a realistic understanding about the number of Virginians who will benefit from enhanced protections and of the level of quality that the Commonwealth can assure them. Consumers need to take prudent steps to educate themselves about their rights and responsibilities. There are several important reasons why this is so:

> State oversight of quality is limited to about 25 percent of the population in Virginia. Federal laws governing Medicare, Medicaid, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), and most important, a large portion of employer-sponsored health benefit plans, limit actions that the Commonwealth can take.
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> ERISA (Employee Retirement Income Security Act of 1974) health plans that are self-funded by employers are exempt from state oversight and regulation. Thus, state statutes and regulations addressing managed care protections will not affect individuals in ERISA plans. The Joint Commission on Health Care (JCHC) has estimated that one third of privately insured individuals are covered by ERISA self-funded plans.
>
> Ideally, the public and private sectors will work together to assure high quality of care in the market. Current laws do not appear to provide adequately for oversight of quality, but

it is important that the Commonwealth balance the legitimate demand for choice, access, and quality with the need to encourage innovation and cost containment by insurers.

Although the current laws appear to address many of the appropriate areas of quality, this report concludes that there are deficiencies in the laws and regulations that need the attention of the General Assembly. The Commonwealth currently has inadequate oversight mechanisms to determine whether health plans are performing in accordance with defined statutes and regulations or with standards these health plans set for themselves. This report concentrates principally on improving current law governing systems-level safeguards. The three general areas that relate to the components of quality and are targeted for improvements include: (1) quality of care assurance/monitoring and improvement, (2) consumer awareness and education, and (3) complaint resolution. The most significant findings of this report are as follows:

Oversight laws have until recently focused on HMOs without including other forms of managed care. It is important that all Virginians enrolled in managed care have the same level of protection. State oversight should be extended on the basis of the functions performed by all insurers.

The *Code of Virginia* requires the State Health Commissioner to examine quality assurance and enrollee complaint systems developed by HMOs, but does not provide adequate authority to address deficiencies. The current Memorandum of Agreement (MOA) between the BOI and the VDH cannot resolve this limitation. The authority granted to the BOI is insufficient to address problems of quality.

More can be done to educate consumers about their health insurance plans. Insurers, providers, consumer groups, patient advocates and purchasers need to develop innovative private-sector methods to educate their constituencies about the existing protections and how they can benefit from them. VDH can assume an educational role limited to assisting and guiding enrollees confused about how to "navigate" themselves through the internal complaint process of their health plan. Finally, providing more information to enrollees about utilization appeals at the time of denial of care and/or through other subscriber communications could be a useful means of educating policy holders.

Chapter 54 of Title 38.2 of the *Code of Virginia* (Chapter 54) contains requirements for a particular type of grievance protection relating to an insurance company's utilization review (UR) or medical necessity decisions. The latter type of grievance is perhaps the most important protection for providers and patients in managed care plans. The BOI lacks regulatory authority for this oversight function, as well as the medical expertise to carry it out. The report presents a possible role for VDH with regard to the regulatory oversight of Chapter 54 appeals.

Private sector initiatives to assure quality have had a significant impact on HMOs. Employers' interest in quality of managed care has given impetus to the development of

accreditation standards and outcome measures for managed care plans. However, national trends suggest that, for employers, quality is a consideration secondary to cost. Private accreditation organizations recommend against states substituting private accreditation of health plans for state oversight obligations; nevertheless, opportunities exist to integrate private accreditation into state oversight of managed care.

II. BACKGROUND

A. Authority for Study

HB 2785 of the 1997 Session of the General Assembly, in its second enactment, directed the State Health Commissioner, in cooperation with the BOI, the Department of Health Professions (DHP), and other state agencies, to study the quality of health care services provided by HMOs. The legislative directive explicitly required that the study: examine quality of care mechanisms currently in place for HMOs and assess the sufficiency of those mechanisms; address to what degree quality mechanisms are in place for other forms of managed care; and consider coordination of the regulatory roles of VDH and BOI, and the appropriate role of VDH and other state agencies in monitoring quality in HMOs. Additional study directives concern HMO complaint systems and whether they should include provisions for provider concerns; whether there is a need for a mechanism for adjudicating controversies or a need for an independent appeals/ombudsman program; and the Commonwealth's role in providing consumer information on managed care issues. (A copy of HB 2785 is provided at Appendix A).

B. Recent History of Quality-Related Managed Care Legislation

Enrollment in HMOs in Virginia has increased rapidly since the late 1980's. The most recent estimate of the Virginia Association of HMOs puts the number of enrollees at 1.38 million. While this number includes enrollees in employer-funded plans that are exempt from state regulation under ERISA, there remain a significant number of Virginians in HMO plans that are regulated by the BOI of the State Corporation Commission.

The first legislation specific to managed care in Virginia was the HMO Act of 1980, incorporated into the *Code of Virginia* as Chapter 43 of Title 38.2. These statutes address licensure and operating requirements for HMOs and the role of the BOI in regulating them.

Since 1995, the Virginia General Assembly has passed the following legislation aimed at protecting consumers and providers in managed care plans:

Chapter 54 was added to Title 38.2 in 1995. These statutes contain requirements for utilization management (UM) and appeals of Utilization Review (UR) decisions made by any health insurer.

Chapter 43 of Title 38.2 was amended in 1994 and revised in 1995 to provide for "freedom of choice" of pharmacies in HMOs; this chapter provides for the inclusion of any pharmacy in an HMO network if the pharmacy agrees to accept the HMO's reimbursement (§38.2-4312.1).

Act of the Assembly, Chapter 776 (House Bill 1393 which passed in 1996), provides for the following: continuity of care for patients whose providers were terminated by a managed care plan; disclosure to purchasers of all reimbursement mechanisms including those that give providers incentives to control utilization of services; and that contracts between managed care plans and providers permit and require the provider to discuss all treatment options with their patients. This legislation also offers provider protections in provisions for disclosure of network development and the terms for inclusion in the network; prohibits "gag orders"; and prohibits contract provisions waiving the provider's right to seek legal redress or requiring a provider to indemnify the MCO for its negligence (§38.2-3407.10).

The definitions section of Chapter 43 of Title 38.2 was expanded in 1995 to include emergency services, which are defined as health care sought in response to symptoms of sufficient severity that a prudent lay person could reasonably expect impairment, dysfunction, or harm to his mental or physical health in the absence of treatment (§38.2-4300).

In 1996, Title 38.2 was amended to include a provision requiring health insurers to permit women direct access to obstetricians/gynecologists without preauthorization for routine services attendant to an annual examination (§38.2-3407.11).

Also in 1996, Title 38.2 was amended to require health insurers to provide post-partum services to mothers and newborns in accordance with criteria of the American College of Obstetricians and Gynecologists and/or the American Academy of Pediatrics (§38.2-3414.1).

In 1997, the General Assembly passed House Bill 2062, requiring HMOs to provide their members 24-hour emergency access to services or to a licensed medical professional by telephone. The legislation requires HMOs to pay for medical screening and stabilization if a representative of the HMO refers a member for emergency services or if the HMO does not have a system for 24-hour access.

The legislation listed above has been enacted; a number of other bills addressing quality of managed care have been introduced in the last three sessions of the General Assembly.

C. 1997 Studies Concerning Quality in Managed Care

In addition to HB 2785, there are currently other studies under way mandated by the General Assembly that address quality in managed care plans:

> Senate Joint Resolution 297 and House Joint Resolution 631 establish a task force to study point-of-service (POS) options for HMO plans. POS options allow HMO members, for additional out-of-pocket costs, to go to out-of-network providers without a primary care provider's referral.
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> HJR 611 requires the BOI, in cooperation with the VDH, to examine statutes and regulations governing HMOs to determine whether their provisions should apply to other forms of managed care plans.
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> Section 54.1-2409.2 of the Code of Virginia directs the Department of Health Professions (DHP) to prepare a report on the appropriate criteria to be used in determining the need for regulation of any health care occupation or profession. The statute directs DHP to examine the current health care delivery system, the current and changing nature of health care settings, and the interaction of the regulation of health professionals with a number of other areas of regulation.
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> In 1996, pursuant to Senate Joint Resolution 67 (SJR 67), the JCHC issued a report on its study of the appropriate role of the agencies of the Commonwealth in overseeing the managed care industry. Three of the options presented in this study were enacted into legislation: (1) the Health Commissioner's role of reviewing HMO quality and HMO complaint systems was changed from discretionary to mandatory by changing the word "may" to "shall" in § 38.2-4315(B) and §38.2-4308(C) of the *Code of Virginia*; (2) the Health Commissioner was requested to report the results and recommendations of VDH's evaluation of its role in overseeing the quality of health care services provided by HMOs to the Joint Commission and the General Assembly; and (3) examination of the need for an independent appeals/ombudsman mechanism for managed care consumers. HB 2785 encompasses all three of these options from the Joint Commission report.

Recent legislative activity in the General Assembly indicates a growing demand among the public at large for state oversight of the quality of care delivered in managed care plans.

D. Roles of the Virginia Department of Health

Although the Health Commissioner has had permissive authority to examine the quality of health care services and the complaint systems of HMOs (§38.2-4307; §4307.B.4; §4308; §4308.B; §4315.B,§ 4316), this prerogative was not exercised until recently.

In August of 1996, VDH convened a round table discussion among stakeholders in the managed care industry in Virginia: providers, advocates and lobbyists, HMOs, and regulators. The focus of the discussion was quality assurance in managed care. The group agreed on seven components of quality, and these components became the organizing principle for the study required in HB 2785 (see below, p. 11).

Shortly thereafter, VDH entered into discussions with BOI in order to properly define and coordinate the role of VDH with respect to BOI's regulatory oversight of HMOs. The result of this collaboration was a MOA between the two agencies that formalizes VDH's participation in monitoring and ensuring quality in HMO plans.

In the 1997 session of the General Assembly, HB 2785 was introduced and passed both chambers with no dissenting votes. The bill changed the Health Commissioner's role from discretionary to mandatory by changing the word "may" to "shall" in §38.2-4308.C. and §38.2-4315(B) with respect to the Commissioner's review of HMO complaint systems and examination of the quality of HMO health services. VDH is additionally charged with receiving and responding to quality of care complaints from managed care enrollees. The bill also required that the Health Commissioner direct an ambitious study assessing the sufficiency of current managed care protections in law and private sector initiatives.

III. METHODS

A. The Process

In order to address the HB 2785 study requirements, a study group was formed representing various state agencies, the health care industry and consumers. Agencies were required to participate in order to provide expertise relative to their particular areas of responsibility. The invitation to private sector representatives was based on their involvement in developing the legislation, the effect that the legislation had on the members of their organizations, or both. Members of the Study Group included the following:

Private Sector

The Virginia Association of Health Maintenance Organizations
The Virginia Hospital and Healthcare Association
Virginians for Patients' Choice
The Medical Society of Virginia
The Virginia Chamber of Commerce

State Agencies

The Department of Medical Assistance Services
The Department of Health Professions
The Virginia Department of Health
The Bureau of Insurance, State Corporation Commission

Although the statute did not become effective until July 1, 1997, the Study Group began meeting in early April and held frequent substantive meetings over the course of six months. In a March 12, 1997, letter, the State Health Commissioner asked the members of the Study Group to identify and gather relevant information on issues referenced in the bill, review and comment on feasible policy options, and assist in drafting appropriate language for the report. In this manner, the Study Group served as an advisory body.

B. The Study Questions

The Study Group developed a work plan (Appendix B) which included four basic questions to address the study instructions. A fifth study question was later added to the work plan to highlight the important efforts underway in the private sector to assure quality of care. The questions posed were as follows:

> What is the current role of the Commonwealth in monitoring and improving the quality of care in HMOs and other forms of managed care?
>
> What private sector activities are currently being undertaken to assure that high quality care is delivered in HMOs and other forms of managed care?
>
> How adequate are the current public and private mechanisms to assure high quality of care in HMOs?
>
> Should all managed care entities be held accountable for quality of care protections?
>
> What is the appropriate role of the Commonwealth in monitoring and assuring the quality of care in MCOs?

C. Research Methodologies to Answer the Study Questions

The approach to this study was developed in accordance with the statutory instructions and the time frame stipulated in HB 2785. More than a dozen separate analyses were undertaken to provide responsive answers to the study requests, involving standard research methods such as statutory analyses, interviews, focus groups (referred to as focused round tables), surveys, selective literature reviews, and the like.

VDH contracted with the UVA, DHES, to conduct objective research to supplement the analyses undertaken by VDH. The DHES efforts included the following:

> An examination of the grievance procedures and quality assurance plans in selected HMOs licensed in Virginia. The analysis compared the systems in different plans with respect to uniformity or disparity, and assessed the shortcomings and merits of each system with respect to regulatory requirements and criteria established by the National

Committee for Quality Assurance (NCQA). Questionnaires were sent to 17 plans; 13 HMOs representing 9 companies completed the questionnaire. (See Appendices C & D for further methodological detail and data).

An examination of quality assurance plans and the grievance procedures in health insurance companies (not HMOs) licensed in Virginia. Questionnaires similar to those provided to HMOs were sent to 15 selected plans. Current quality of care and grievance procedures of selected PPOs were requested in order to validate the answers given by representatives of the plans. These plans were compared to indicate areas of uniformity and disparity and were assessed based on state regulatory requirements and criteria established by the American Accreditation Health Care Commission, formerly known as the Utilization Review Accreditation Council (AAHCC/URAC). For the quality assurance plan review, three companies completed the questionnaire, and four additional companies reported that they do not have quality assurance plans due to the type of coverage written. For the grievance procedures review, five companies completed the questionnaire, and four additional companies responded that they do not have grievance procedures (Appendices E & F).

Design of a short survey in consultation with the BOI and the VDH for 232 of almost 1000 entities subject to the provisions of Chapter 54, which covers managed care UR requirements and appeals for denied coverage. Thirty-one surveys were sent to HMOs and 200 were sent to other health insurance companies. The purpose of the survey was to assess the number of times the companies had processed appeals using the provisions of Chapter 54, reasons for using or not using these provisions, and willingness to provide information about Chapter 54 proceedings to the BOI. Fourteen HMOs and 106 other health insurance companies responded to the survey. (Appendix M)

A "Consumer Awareness" survey to determine Virginia consumers' awareness of their rights and responsibilities pertaining to complaints, grievance procedures provided by their health plans, and protections afforded to consumers under existing state law. DHES subcontracted with the Southeastern Institute of Research in Richmond to design, execute and analyze a randomized survey of consumers of health insurance in the Commonwealth (Appendix G)

The following research activities were undertaken by VDH:

In cooperation with BOI, the DMAS, the DHP, the Department of Personnel and Training, and private sector members of the Study Group, VDH reviewed and assessed the federal and state laws and regulations governing consumer complaints (Appendix H).

In cooperation with the Study Group, VDH reviewed the Virginia laws and regulations governing the quality of care in MCOs (Appendix I).

The VDH Center for Quality Health Care Services and Consumer Protection developed a quality of care complaint classification system to be used by the state agencies in order to support a coordinated statewide grievance oversight system. This classification system is a first step towards capturing information in a uniform manner. In addition, the center developed a protocol for responding to complaints referred by BOI. Finally, VDH undertook a preliminary analysis of individual complaints[3] (84 between December 1996 and October 1997) referred by BOI in accordance with this classification system to assess whether current law provides a sufficient basis to determine the merits of the allegation (Appendix J).

Three focused round tables were convened to learn more about the problems (real and perceived) that providers and consumers have with managed care plans. The provider focused round table included 16 health professionals. Nominations were made by the Medical Society of Virginia and the DHP, with VDH making the final selection. The HMO focused round table involved the complaint managers and other representatives of 13 plans, based on nominations by the Virginia Association of HMOs and final selection by VDH. The consumer focused round table involved 19 individuals from large and small businesses, patients, representatives of consumer organizations, and complaint managers from the state agencies (Appendix K).

Interviews with other states on selected topics relevant to HB 2785 were conducted. One study analyzed the quality of care activities of eight states where the insurance and health departments have shared oversight responsibilities (Appendix L). Another study described selected states which had an ombudsman or a consumer appeals process external to HMO internal complaint systems (Appendix L).

D. Defining Quality of Care

Quality is a difficult term to define, but for consumers and providers, it is the most crucial aspect of health care delivery. What constitutes quality is debatable, but most would agree to certain fundamental attributes that must be encompassed by any definition of quality. The Institute of Medicine (IOM) formed a prestigious committee to define quality of care. After reviewing more than 100 definitions presented by experts over the years, it identified several key dimensions which it believed were critical. These key dimensions include: a scale of quality, the type of recipient of care, risk versus benefit tradeoffs, the role and responsibility of the recipient, constraints of technology, interpersonal skills of providers, accessibility, acceptability, resource constraints, and continuity. Incorporating these aspects, the IOM developed its own consensus definition: "quality of care is the degree to which health services for individuals and populations

[3]Most of these complaints are pending investigation. Confidentiality has been preserved. The interests of this study focus on the adequacy of the authorities on which investigation of individual complaints can go forward, not the specifics of the allegation nor actual number of the complaints.

increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[4]

The HB 2785 Study Group debated the feasibility of attempting to define quality of care given the time constraints for conducting the study and concluded that it was reasonable to adopt a definition of quality that had continuity with Virginia's health regulatory history. The definition contained in the *Virginia Health Facilities Plan* was judged to be an adequate working definition for purposes of this study:

> Quality of care means the degree to which services provided are properly matched to the needs of the population, are technically correct, and achieve beneficial impact. Quality of care can include considerations of the appropriateness of physical resources, the process of producing and delivering services, and the outcomes of services on health status, the environment and/or behavior. (12VAC5-230-10)

This working definition incorporates many of the key dimensions identified by the IOM and is compatible with the seven elements of quality adopted during the State Health Commissioner's *Round Table Meeting on Quality of Care in Network-Based Health Delivery Systems* (August 1996). These seven quality of care components were adopted as appropriate areas for state oversight include: **(1) complaint resolution and consumer satisfaction; (2) access, availability, and continuity; (3 prevention; (4) credentialing; (5) consumer/provider education and awareness; (6) outcome measures and accountability; and (7) improvement of community health.** All but the seventh component of quality were used as organizing principles for many of the analyses undertaken in the study. However, there are still unresolved issues surrounding the definition and meaning of the quality components.

IV. HOW DOES THE FEDERAL ROLE IN HEALTH CARE AFFECT STATE OVERSIGHT OF QUALITY OF CARE IN MANAGED CARE PLANS?

The United States Congress has been on a parallel course with many states in questioning the extent of consumer protections in managed care. In addition, President Clinton recently established a 32-member "Advisory Commission on Consumer Protection and Quality in the Health Care Industry." The Commission is charged with reviewing the available data on consumer information and protections and making appropriate recommendations for improvement; reviewing existing data and recommending approaches to assure and promote quality of care in a changing delivery system; and collecting and evaluating data on changes in availability of services, and making recommendations for improvements. The Commission is broadly represented by consumers, business, labor, health care providers, insurers, and experts on

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[4]Institute of Medicine, *Medicare: A Strategy for Quality Assurance, volume I* (1990), p. 21.

health care quality and financing. Its first task is to develop a "Consumer Bill of Rights" to ensure that patients have adequate appeals and grievance processes. In addition, the Commission will review legislative initiatives pertaining to quality and consumer protection.

As the study directive in HB 2785 requires an examination of state oversight of managed care, it would be beyond the scope of this study to analyze federal quality and grievance protections in detail. Considerations regarding the state regulation of managed care do not apply to all managed care plans in Virginia. Self-funded employee welfare benefit plans (29 *United States Code*, §1002(1)) are exempt from state insurance laws pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA)(29 USC §1144). In addition, federal and state benefit programs such as Medicare and Medicaid may also be exempt from some or all state regulation. As a result, state regulation of managed care principally affects the commercial market only, which represents approximately 25 percent of the overall health care market in Virginia, according to an estimate made by the JCHC. The following is a review of significant points about federal oversight of managed care:

A. ERISA

The Employee Retirement Income Security Act of 1974 (ERISA) contains the requirements for health plans funded by private employers. This legislation affects all private sector group health plans, not just the plans that are "self insured." ERISA preempts state laws that "relate to" employee benefits plans (29 USC §1144(a)(1988)); however, state laws regulating the business of insurance are not preempted through ERISA's "savings clause." The courts have interpreted these two clauses to mean that states cannot regulate employee benefits directly, but can regulate the insurers that contract with employers. This distinction between commercially insured and employer self-funded health plans was made by the United States Supreme Court in *Metropolitan Life Insurance Company v. Massachusetts.* The Court held that the state could mandate which benefits a health insurance company had to offer, but could not mandate benefits for self-insured plans.

For the purposes of the HB 2785 study, the most significant point about self-funded plans is that they cover the largest number of insured Virginians, 35% of the population, according to the estimates by the Joint Commission. Beneficiaries of these plans are not entitled to the state oversight protections discussed in this report.

The U.S. Department of Labor (DOL) administers ERISA in accordance with federal regulations at 29 CFR §2510.3-1-2500.408b-2. There are no mandated benefits for ERISA plans; employers may choose which health care services will be offered. It is required that participants and beneficiaries be informed about the extent of their benefits and their rights under the plan. They must also be informed of procedures for filing claims, the basis for claim denials, and procedures for appealing denials.

The DOL will take action on problems that affect the entire membership of a self-insured plan, but does not get involved in conflicts concerning benefits between an individual and a plan. DOL's assistance to individuals is primarily in the form of information about their rights under ERISA. Beneficiaries of employer-funded health plans may take their disputes to federal court, but can only collect the cost of a denied benefit, and, in some cases, attorneys' fees.

Because of the minimum standards imposed by ERISA and the preemption of state regulations, consumers in employer-funded health plans may have fewer protections than Virginians in commercially insured plans (Appendix H, p.8-11)**.**

B. Medicare

The Code of Federal Regulations (CFR) provides for enrollment of Medicare beneficiaries in HMOs, Competitive Medical Plans, and Health Care Prepayment Plans. In Virginia there are approximately 10,105 Medicare beneficiaries in HMO plans according to a 1997 estimate of the Virginia Association of HMOs. Part 417 of 42 CFR details the many requirements for health plans seeking contracts for Medicare beneficiaries. A quality assurance program is required at 42 CFR §417.106 that includes a focus on "state of the art" health outcomes; requirements for accessibility and continuity of care; and collection of data on performance and patient results.

The Health Care Financing Administration (HCFA), the federal agency with regulatory oversight of the Medicare program, requires states to contract with Peer Review Organizations (PRO) that perform mandated reviews of all beneficiary complaints concerning quality of care. The PROs have the authority to recommend sanctions through HCFA. The PRO must also review any decision by a hospital or managed care plan to terminate services where the beneficiary would be liable for the cost of the care. Any other medical necessity determinations are reviewed by the Center for Dispute Resolution, another independent review organization.

Medicare beneficiaries also have the right of independent appeals and grievances. If the dispute involves an amount of $100 or more, the beneficiary has the right to a hearing by an administrative law judge; if the amount in controversy exceeds $1,000, the beneficiary is entitled to judicial review of the hearing. Grievance and appeal rights are set forth in §1869 of the Social Security Act and in CFR, §417.600 - §417.694. (Appendix H, p. 39)

C. Medicaid

HMOs that enroll Medicaid beneficiaries in Virginia are regulated by the Department of Medical Assistance Services (DMAS) and HCFA in addition to the State Corporation Commission's BOI. The CFR requires that HMO contracts contain provisions specifying that the Medicaid agency evaluate, through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract, and that contracts require HMO participation in an annual independent external review of the quality of services furnished under the contract(42 CFR §434.6(a)(5), §1902(a)(30)(C) of the Social Security Act). In addition, 42 CFR §434.34 requires

that HMOs contracts provide for: "an internal quality assurance system that is consistent with the utilization control requirement of part 456 of CFR; provides for review by appropriate health professionals of the procedures followed in providing health services; provides for systematic data collection of performance and patient results; provides for interpretation of these data to the practitioners; and provides for making needed changes." 42 CFR at §434.53 assigns to the Medicaid agency the responsibility of periodic medical audits, at least annually, and the collection of data that includes reasons for enrollment, disenrollment, termination and use of services. The state Medicaid Manual and §1902 (a) (30)(C) of the Social Security Act specify the types of entities eligible to perform external review.

Medicaid recipients are entitled to a formal independent appeal process. Beneficiaries enrolled in HMOs may use their HMO's grievance procedure but may appeal directly to DMAS if they choose. A formal grievance is required to be initiated in writing. Should the grievance proceed to a hearing, the decision will be rendered by a DMAS hearing officer and will be binding. Medicaid grievance rights and procedures are found at 42 CFR §431.200 - §431.246.

V. WHAT IS THE CURRENT ROLE OF THE COMMONWEALTH IN MONITORING AND IMPROVING THE QUALITY OF CARE IN HMOS AND OTHER FORMS OF MANAGED CARE?

There are several agencies involved with the oversight of the quality of care provided by MCOs. The DHP is responsible for the licensing of practitioners that may have contracts with MCOs. It also receives and investigates complaints on practitioners regulated by the respective professional boards (Appendix H, p. 31). In addition, the BOI and the VDH have oversight responsibilities affecting the plans. Their roles are briefly discussed below. (Appendix H also examines their roles with respect to complaints and grievances.)

A. State Agencies with Oversight of HMOs

1. The Bureau of Insurance (BOI)

The BOI of the State Corporation Commission is the primary agency involved in regulatory oversight of managed care, responsible for licensure and compliance with state laws for all companies in the business of insurance in the Commonwealth. As provided by statute, the BOI initiates financial and market conduct examinations of all domestic health insurers at least every five years, focusing on financial solvency; marketing, sales and claims practices; business practices; and the systems in place for regulatory and statutory compliance. An important quality aspect of the market conduct examination is the review of complaint records maintained by the insurance company and a comparison of these records to the BOI's internal records of complaints brought to the Bureau by consumers.

In addition to financial and market conduct examinations, the BOI also targets investigations of insurance companies where there is indication of noncompliance with applicable law. For

example, the BOI's Life and Health Consumer Services Section investigates complaints about insurance companies brought by individual consumers. While the BOI advocates on behalf of a consumer and provides information relevant tocomplaint resolution, it does not adjudicate individual complaints. If the BOI finds a violation of a law, it may require remedy to individuals as part of its settlement with the insurance company. In this way, the BOI functions similarly to an ombudsman; however the BOI does not have the authority to adjudicate disputes concerning an insurer's contractual obligations or UR decisions.

The BOI requires that health insurance carriers keep records of complaints for three years or since the date of their last market conduct examination, whichever is the more recent time period. The record must indicate the classification of complaints by line of business, the nature and disposition of each complaint, and the time it took to process each complaint.

With respect to HMOs and other forms of managed care, the most substantial difference in oversight activities of the BOI concerns initial licensure, for which HMOs have requirements in addition to those of other insurance carriers. These additional requirements reflect the fact that HMOs provide a delivery system for care in addition to reimbursement for care. Most significant are the requirements for complaint procedures, QA plans and provider networks. The BOI must ensure the adequacy of the HMO's provisions for these aspects of health care delivery. HMOs are also required to provide annual complaint reports to the BOI. The report must include a description of the complaint system procedures; the total number of complaints processed through the system; a compilation of causes for the complaints; and an accounting of the malpractice claims settled or adjudicated during the year by the HMO and any of its health care providers.

2. The Virginia Department of Health (VDH)

The VDH has no statutory or regulatory authority over health insurance companies that are not licensed as HMOs. It has only very recently become involved in HMO oversight, chiefly through the execution of the MOA signed by the BOI and VDH in January of 1997(Appendix N).

The MOA between VDH and BOI is prefaced by reference to the Health Commissioner's statutory authority in Chapter 43 to examine the quality of health care services and complaint systems of HMOs. The agreement provides that VDH will assist the Bureau by on-site and administrative review of QA issues; that VDH will participate in market conduct examinations; and that the Bureau will provide advice and expertise as requested. The MOA requires that VDH review and approve HMO complaint systems for licensure and that VDH monitor and report HMO providers who are not in compliance with licensure regulations addressing quality of care. VDH is also required to review HMO QA and UR programs both as part of licensure and as needed, and to review HMO network adequacy. VDH responsibility for on-site reviews encompasses the grievance and complaint systems, the QA program, and the medical delivery system.

Prior to the effective date of HB 2785, the VDH had been conducting quality complaint investigations about HMOs under the MOA. Subsequent to its enactment, the VDH is receiving and responding to quality of care complaints from managed care enrollees as directed by the mandate. Complaints about all MCOs are referred to VDH from the BOI in accordance with a detailed protocol for developed as part of this study by the VDH's Center for Quality Health Care and Consumer Protection (Appendix J).

Finally, with the passage of House Bill 1307 in the 1996 General Assembly, the oversight for health care data reporting has recently become a responsibility for the VDH (Chapter 7.2 of Title 32.1). The VDH exercises that responsibility through its health data reporting contractor, the Virginia Health Information, Inc. (VHI). The VHI is a nonprofit, tax-exempt health data organization that develops and implements health data projects that provide useful information to consumers and purchasers. Data initiatives, such as publication of consumer satisfaction reports using Health Plan Employer Data Information Set (HEDIS), are presented in its 1997 *Strategic Plan*. Unlike the health data reporting requirements imposed on hospitals and nursing homes, the HEDIS data initiative is voluntary.

B. State Laws and Regulations Providing Quality and Grievance Protections

In order to describe the Commonwealth's role in monitoring and improving the quality of care in HMOs and other forms of managed care, it is helpful to use the consensus components of quality adopted by the Study Group. These components are: (1) complaint resolution and consumer satisfaction; (2) access, availability, and continuity; (3) prevention; (4) credentialing; (5) consumer/provider education and awareness; (6) outcome measures and accountability; and (7) improvement of community health. (See Appendix I for a detailed description of the statutes and regulations addressing quality of care.). This section begins with a discussion of quality in general, followed by an examination of six of the seven components of quality.

1. Quality in General

Requirements for a QA plan or program are unique to HMOs in Virginia statutes and regulations; there are no similar requirements for other insurance entities. The State Health Commissioner is required to examine the quality of health care services of all HMOs licensed in the Commonwealth and the providers with whom they contract as often as considered necessary for the protection of the citizens of the Commonwealth. The Health Commissioner is also given the authority to certify to the State Corporation Commission (SCC) that an HMO cannot provide quality health services.

The *Code of Virginia* and *the Virginia Administrative Code* contain the same language regarding the HMO's QA plan. No specific requirements are necessary in the plan, only that the HMO has a plan that provides for adequate resources and assessment of the quality of care.

2. Complaint Resolution and Consumer Satisfaction

The enactment clause of HB 2785 contains a provision requiring the VDH "to receive and respond to" complaints from managed care plan enrollees regarding quality of care issues. This is the only statutory language that differentiates a quality of care complaint from any other type of complaint and the only statutory language expanding the Health Commissioner's purview from HMOs to other forms of managed care.

HMOs are required to have an enrollee complaint system and to submit annual complaint reports. The complaint system must be approved by the State Health Commissioner and the BOI. Administrative law further details the requirements for the complaint system, including the requirement that grievances be resolved in 180 days. The importance of the complaint system is reflected in the statutory provision for suspension of licensure if the HMO fails to implement a complaint system in accordance with the requirements of Chapter 43 of Title 38.2.

There are no statutes or regulations requiring that health insurers other than HMOs have grievance systems or procedures. All insurance companies are required to maintain complete records of all complaints since the last market conduct examination or for the last three years, whichever is the more recent time period. A "complaint" for commercial carriers is defined as any written communication expressing a grievance.[5]

Chapter 54 of Title 38.2 (Chapter 54)[6] applies to all health insurers that perform UR, which is the determination of whether covered services are medically necessary. Chapter 54 provides for the patient's provider to appeal UR decisions, and thus, addresses one of the most important aspects of complaint resolution for consumers in managed care plans. Except for expedited appeals, Chapter 54 requires that final appeals of UR decisions be made by a peer of the treating physician who is not employed by or a director of the insurance entity, and who was not previously involved in the UR decision at issue. The physician peer is required to be board certified or board eligible in a specialty pertinent t the issue under appeal.

Concerning consumer satisfaction, statutory requirements limited to HMOs require allowing covered persons their choice of primary care providers (PCPs) and require mechanisms permitting consumer participation in policy and operations.

3. Access, Availability, and Continuity

HMOs are required to file contracts and provider lists with the Bureau, as a condition of licensure. This enables the Bureau to assess the accessibility, and to some degree, the adequacy of the network. The *Code* further requires that the list of providers with whom the HMO has contracts be updated quarterly and filed with the Bureau. The regulations define standards for

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[5] Regulations for the Medallion II managed care programs contain definitions of "appeal" and "grievance", but do not define "complaint" (12VAC 30-120-360)

[6] Chapter 54 does not apply to Medicare, Medicaid, and CHAMPUS.

access to care and there are several HMO statutes that specifically address access to emergency services.

All health insurers have a number of requirements imposed on them addressing access to specific providers, such as pharmacies, podiatrists, and obstetricians and gynecologists, and all are bound by the same length of stay requirements for maternity care. The "Patient Protection Act" (*Code*, §38.2-3407.10), which makes provisions for continuity of care and requires disclosure of treatment options and disclosure of provider panels, likewise applies to all health insurers.

4. Prevention

In statute, HMOs are required to provide preventive care services described in the definitions section of Chapter 43 of Title 38.2. For all other health insurers, the preventive services mandated include well-child care, mammograms and Pap tests. The most strenuous requirements for preventive services apply to the Essential Benefits Plan, and this is only applicable to the small group market (50 or fewer employees).

5. Credentialing

There are no statutes or regulations requiring HMOs or other insurance companies to credential their providers. The laws only stipulate which practitioners and facilities must be licensed by the state and provide for reporting of disciplinary actions taken against practitioners by certain health care institutions.

6. Consumer/Provider Education and Awareness

In regard to consumer awareness and disclosure requirements, there are many more legal requirements for HMOs than for other health insurers. HMOs have specific disclosure requirements for their EOC including covered services and limitations; limits on out-of-pocket payment by the consumer; grievance procedures; and participating providers.

All health insurers are required to disclose the UR process contained in Chapter 54. They are also required to notify purchasers of the payment mechanisms used for provider reimbursement. At least annually, all health insurers must provide purchasers with a list of the current providers contracted with the plan, indicating those who are not accepting new patients. All health insurers are required to disclose in their policies or contracts information on how to contact the BOI if they are unable to resolve their concerns with their insurance company or agent.
All health insurers are required to disclose in their policies or contracts information on how to contact the BOI if consumers are unable to resolve their concerns with their insurance company or agent.

7. Outcome measures and Accountability

There are no outcome measures or data required of HMOs only. The *Code of Virginia* makes provisions for health care data analysis and reporting in Chapter 7.2 of Title 32.1. This initiative is cited in the *Code* as "essential to the improvement of the quality and cost of health care in the Commonwealth," and delegates the responsibility of administration of this initiative to the State Board of Health (BOH) and the Health Commissioner. Because health insurance companies are included in the definition of "provider" for the purposes of this data initiative, this legislation does provide for voluntary reporting of outcome measures or data from all managed care entities; however, technical problems with the data sources will have to be resolved before consumer information on health plans is available through this source (Appendix O).

VI. WHAT PRIVATE SECTOR EFFORTS ARE CURRENTLY BEING UNDERTAKEN TO ASSURE HIGH QUALITY OF CARE IN HMOs AND OTHER FORMS OF MANAGED CARE?

This section describes private sector quality systems developed in response to employer concerns about the quality of managed care. These concerns precipitated the development of national accrediting organizations such as the National Committee for Quality Assurance (NCQA) and the AAHCC, who share the mission of assessing quality in managed care plans. This section also describes approaches to QA used by self-funded employers and integration of private and public sector quality oversight mechanisms. (Summary of NCQA & AAHCC's presentations to the Study Group are in Appendix J)

A. National Quality Accreditation Organizations

1. National Committee for Quality Assurance (NCQA)

The NCQA is a private, not-for-profit organization whose mission is to assess the quality of managed care plans. As of May 1996, NCQA had accredited 333 of the estimated 574 HMOs in the United States. According to the 1997 Directory of Virginia HMOs, six Virginia-licensed plans have full three-year NCQA accreditation, plans, eleven plans have provisional or one year accreditation, four plans are seeking or planning accreditation review, and eight plans have an unavailable status.

NCQA's purpose is to provide information that enables purchasers and consumers of managed health care to distinguish among plans based on quality, thereby allowing them to make more informed health care purchasing decisions. Their efforts are organized around two primary activities, accreditation and performance measurement, which are complementary strategies for producing information to guide purchaser decision-making. NCQA began accrediting MCOs in 1991. Since then, they have expanded the range of organizations that they accredit to include managed behavioral health care organizations, credentials verification organizations and physician organizations.

For an organization to become accredited by NCQA, it must undergo a survey and meet certain standards designed to evaluate the health plan's clinical and administrative systems. In particular, NCQA's accreditation survey looks at a health plan's efforts to continuously improve the quality of care and service it delivers.

During an accreditation survey, plans are reviewed against more than 50 different standards, each of which focuses on an important aspect of health care delivery and consumer satisfaction. These standards fall into six broad categories: quality management and improvement; credentialing; member rights and responsibilities; prevention; UM; and medical records.

The standards are "state of the art," and accreditation is a rigorous process; a health plan must be aggressively managing quality to achieve full accreditation. As of April 30, 1997, approximately 53% of all HMOs in the nation were involved in the NCQA accreditation process. The NCQA reports that the base price is around $30,000 for a plan with 50,000 members.

NCQA produces Accreditation Summary Reports to further aid consumers and employers. These reports demonstrate a plan's degree of compliance with the standards in each of the six broad categories, and show how the plan performed compared to the national average.

Where accreditation standards are measures of the structure and processes an organization has adopted to ensure quality of care, the HEDIS is a measure of the outcomes of care. HEDIS are a set of standardized performance measures that assess effectiveness of care, accessibility and availability of care, member satisfaction, cost of care, health plan stability, informed choices, use of services, and plan descriptive information. NCQA uses these categories as part of a standard report card for managed care plans. (See Appendix P for a summary of accreditation organization standards)

2. American Accreditation Health Care Commission (AAHCC/URAC)

The organization was formally chartered February 14, 1990, as the Utilization Review Accreditation Commission, Inc., a 501© (3) not-for-profit corporation. It was specifically formed to develop national standards for the UR industry.

In 1995, URAC acquired the American Accreditation Program, Inc. (AAPI). AAPI had developed standards specifically aimed at the PPO industry and accredited a number of PPO programs in the early 1990s. URAC assimilated elements of the AAPI accreditation standards into its own network standards, which are generally applicable to the entire managed care industry, but are especially appropriate for evaluating PPOs and point of service (POS) plans.

In March 1997, URAC changed its corporate name to American Accreditation Health Care Commission, Inc. (AAHCC) to more accurately describe its expanding role as an accreditation company for a wide variety of MCOs. AAHCC currently offers programs in three areas: 1) provider networks and health plans; 2) UM; and 3) workers' compensation managed care.

The network standards address provider network management and participation; quality management; UM; credentialing; and member participation and protection**.**

AAHCC original UR standards were revised in 1994 to provide a more stringent level for review and to address a broader range of issues and concerns. These standards address: program qualifications; quality improvement programs; confidentiality; staff qualifications and credentials; UR procedures; UM staff accessibility; on-site review procedures; information requirements; and appeals. AAHCC grants full accreditation for two years.

B. Self-funded Health Plan Initiatives

ERISA requires relatively few standards in the administration of self-funded health benefit plans. Administrators are held to fiduciary standards and required to administer the benefits according to the plan document. ERISA requires that plan beneficiaries be apprised of covered benefits, information about changes, eligibility requirements, the name of the organization administering the benefits, procedures for claims payments, and remedies available when claims are denied.

In spite of limited requirements under ERISA, many large and mid-size employers that self-fund their employee's health benefits are using their purchasing clout to choose health plans that are privately accredited. Employers typically contract for the services with a health plan that functions as a third party administrator (TPA). TPAs assume a range of administrative services including claims adjudication, customer service, UR, and provider network management. The employer may select the benefits to be offered or may select a plan currently marketed by the managed care entity. There are no coverage mandates under ERISA, so employers are free to offer their choice of benefits.

The employer's emphasis on quality is likewise discretionary. With respect to grievances, the employer may have human resources staff assigned to assisting employees with their benefits who can advocate on their behalf with the TPA. The final decisions on whether or not a service is to be covered will rest with the employer, although many employers will not get involved in these conflicts.

While actual numbers are not available for Virginia, a number of employers are interested in the quality of the managed care entity with which they contract for administrative services. Typically, the employers are interested in the provider network, particularly the accessibility to PCPs and hospitals. Employers may require separate customer service tracking systems for their employees and have specific standards regarding response time on the telephone. Accreditation by NCQA or similar organizations has increasingly come to be viewed as an imprimatur of quality, and accreditation status may be an important consideration for a large employer contracting for Administrative Services Only (ASO) services. Included on NCQA's list of national companies requiring and requesting NCQA accreditation surveys are Allied Signal,

Bristol Myers-Squibb, Chrysler, Digital Equipment, Ford, GE, IBM, Mobil, Nations Bank, PepsiCo, Procter & Gamble, UPS, and Xerox.

With the advent of HEDIS, employers have an even more specific measure of quality than accreditation status. Where accreditation examines a health plan's structures and systems, HEDIS measures the plan's performance, the results actually achieved by the plan. NCQA has developed a "Quality Compass © " to assist employers in choosing health plans on the basis of quality and value.

However, there are indications that for many employers quality is a secondary consideration to cost. The Wall Street Journal cited a KPMG Peat Marwick national survey indicating that "employers are giving a short shrift to widely touted attempts to measure the quality of health care plans." The survey reportedly revealed that employers are not paying much attention to attempts to measure the quality of MCOs and found that only 40% of employers rated NCQA accreditation as an important factor for choosing a health insurance plan (*Wall Street Journal,* 6/18/97). A national survey by the Washington Business Group on Health and Watson Wyatt Worldwide Consultants of 368 employers indicated that 53% of employers equate health care value with cost, but only 39% equate value with quality. This study also purportedly found that only 8% of the employers correlated value of a managed care plan to its accreditation status.[7]

C. Integration of Private Sector and Public Sector Standards

Because of ERISA's preemption of state laws, states and consumers have expressed concern about the ability of states to protect employees in self-insured plans. The federal DOL does not provide the level of individual complaint investigation typically provided by state insurance regulators. However, DOL has been seeking public comment on existing regulations on benefit claims procedures governing the health benefits of about 125 million Americans. Likewise, an NGA policy brief also calls upon the U.S. Congress to create new opportunities for states to assess the adequacy of consumer protections under ERISA. It proposes two options to address to accomplish this policy objective:

> Congress should work with the states to establish national health care standards for self-funded plans that are similar to those imposed by states on commercial plans. If Congress is unwilling to define legislative standards in ERISA, the U.S. DOL, in conjunction with the states, should be given the authority to develop and enforce regulations that, at the very least, establish essential consumer protections and remedies standards for self-funded plans.
>
> Anecdotal evidence suggests that consumer protection problems are more likely to arise in small self-funded plans. Congress could limit self-funding authority to businesses above a certain size. Businesses below that limit

[7] *Managed Care Stats and Facts* (April 1, 1996)

> would be required to follow state laws. The U.S. DOL would need to enforce standards for those plans that remain under its jurisdiction (NGA, 1997).

Some states are attempting to work with employers and the federal government to investigate complaints in self-funded plans. For instance, Oklahoma and Maryland are currently working in partnership with the federal government to investigate consumer complaints in ERISA plans.

Currently, no states require NCQA accreditation for licensure. However, some states do require a quality review for licensure, which NCQA is licensed to perform. These states are Florida, Kansas, New Jersey, Oklahoma, Pennsylvania, Rhode Island, South Carolina, and West Virginia. In about half of these states, regulators accompany the NCQA survey team. There is also a handful of states (Alabama, New York, Ohio, Tennessee, and Virginia) that require an MCO to have NCQA accreditation in order to have a contract with a state agency. There are no states that accept NCQA accreditation in lieu of licensure.

Another approach to integration of public and private standards is for states to incorporate NCQA or AAHCC standards into state licensure or certification procedures. Some states are using AAHCC accreditation status as an element of the regulatory process for HMOs, UR companies, and health insurers performing UR. Sixteen states and the District of Columbia recognize AAHCC/URAC standards and accreditation: Alabama, Arizona, Connecticut, District of Columbia, Georgia, Indiana, Iowa, Kansas, Maine, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Rhode Island, and Tennessee.

Although there are advantages to integrating private accreditation organizations into the state responsibility for oversight, neither NCQA nor AAHCC recommends that private accreditation be a substitute for state oversight. In an NCQA report (Winter 1995-96) entitled *States' Roles in Monitoring Quality Evolving,* Stephen Lamb, Assistant Vice President, set forth the position in this manner:

> There is an important distinction between requiring health plans to *undergo* an accreditation review, and requiring health plans to *pass* accreditation as a condition of licensure. With more than half the nation's HMOs still unsurveyed, NCQA opposes efforts to directly link a health plan's licensure status to the outcome of an accreditation review. Nor does NCQA advocate 'deemed status' in the traditional sense of a statutory requirement for regulators to accept evidence of particular accreditation body's decision as meeting state requirements. NCQA supports giving state officials the flexibility to approve, and periodically reevaluate, independent accreditation bodies to ensure coordination and consistency over time. Originally pioneered in Pennsylvania, this approach has now been adopted by nearly every state incorporating private accreditation review processes into the HMO regulatory scheme.

Likewise, Guy D'Andrea, Director of Policy for AAHCC, stated that "final decisions about licensing or certification should be left to the state. This preserves both the integrity of the accreditation review process and the autonomy of the state."

VII. HOW ADEQUATE ARE THE CURRENT PUBLIC AND PRIVATE QUALITY OF CARE MECHANISMS TO ASSURE HIGH QUALITY OF CARE IN MANAGED CARE ORGANIZATIONS?

This section of the report analyzes the adequacy of the oversight for current quality of care mechanisms and is divided into four parts. The primary focus is on the oversight of processes and systems which commercial health plans use to assure and improve quality of care. The first part examines general provisions for quality and the sufficiency of the MOA between BOI and VDH to permit assessment of quality compliance. The second part analyzes the statutes and regulations addressing the components of quality. The third part examines the provisions of Chapter 54. These statutes address UR (medical necessity) determinations made by managed care companies and provide for appeals of those decisions. The special emphasis on Chapter 54 is due to the importance these statutes have for consumers whose insurers deny coverage for health care services that the treating practitioner believes are necessary. The fourth part addresses concerns expressed by providers who participate in managed care plans.

The analysis in Section VII is done with reference to the compilation of statutes and regulations in Appendix I. These laws address quality of care in general and are organized according to the components of quality identified by the study group. The focus is on those statutes and regulations that pose special problems to the minimum requirements necessary for the state to exercise its oversight of quality of care in managed care plans.

For each issue discussed, relevant research is included, much of it conducted by the University of Virginia, DHES. DHES examined QA and grievance plans of MCOs and conducted interviews with the plans to gain additional information (Appendices C, D, E, and F). DHES also conducted a survey of insurers concerning Chapter 54 (Appendix M) and contracted with Southeastern Institute of Research, Inc. to perform a consumer awareness survey (Appendix G). In addition to the work done by DHES, Section VII also includes results of the focused round tables held by VDH, and other research.

A. General Issues Related to the Quality of Care

The BOI has experience in regulating solvency and other financial operations of indemnity carriers, but the clinical expertise necessary to evaluating the quality of health care services is absent. The JCHC's study pursuant to SJR 67 included the observation that "some aspects of managed care plans are outside the scope of traditional insurance regulation" including UR, medical necessity determinations, access, and "quality of care" issues.

1. Advantages and Limitations of the MOA

In January 1997, the BOI and the VDH entered into an interim MOA allowing the two agencies the authority and expertise to examine quality in HMOs. The purpose of the MOA was to create a pilot project whereby VDH could complement its experience in assuring the quality of care delivered in health facilities with the experience of BOI in regulating managed care plans. Because VDH had no regulatory guidance to implement existing statutes, the MOA provided a mechanism whereby the two agencies could discover issues in regulating the quality of care in HMOs. The two agencies understood that the State Health Commissioner probably could not effectively discharge his responsibilities under existing BOI authority and that regulations would be necessary to provide minimum oversight of quality of care. Nevertheless, the MOA allowed the agencies to identify potential regulatory problems (including the complex issues surrounding enforcement), explore possible solutions, and coordinate HMO examinations of quality and complaint investigations to achieve an appropriate level of regulatory oversight without duplication.

Despite these obvious advantages, the MOA had several limitations, which make it an undesirable long-term mechanism. These shortcomings exist because many of the challenges associated with regulating quality of care cannot be addressed adequately through the existing BOI statutory and regulatory authority. Establishing an MOA cannot create new authority for the VDH that does not already exist at the BOI. One limitation is that the current authority is deficient where issues of quality care arise. Second, the Health Commissioner has little authority independent of the MOA to compensate for these deficiencies. Third, sanctions available to the BOI and the State Health Commissioner to assure quality are inadequate. The only sanction available to the Health Commissioner is to recommend that the SCC revoke or suspend an HMO's license. The BOI's authority primarily addresses solvency, advertising, and trade practices, none of which are appropriate for addressing an HMO's improper attention to quality of care. Finally, it is inappropriate for the BOI to enforce VDH's findings of noncompliance.

2. Laws Pertaining to General Quality Issues

While the *Code* gives the State Health Commissioner broad authority to examine the quality of care in HMOs, it does not provide for regulations to be promulgated pursuant to this section. Absent appropriate regulations, VDH cannot establish standards for evaluating the quality of care in HMOs and cannot effect compliance**.**

Section 38.2-4316 of the Code addresses conditions for which the BOI may suspend or revoke an HMO's license. Section 38.2-4316.4 allows for suspension or revocation if "[t]he State Health Commissioner certifies to the Commission that the HMO is unable to fulfill its obligations to furnish quality health care services as set forth in its health care plan consistent with prevailing medical care standards and practices in the Commonwealth. . . ."

This section, too, is unsupported by any regulations, and there are no state standards by which the Health Commissioner can evaluate the HMO's ability to "furnish quality health care services." "Prevailing medical care standards" are not defined in regulation; presumably what is meant is

the standard of care, the standard to which all licensed practitioners are held in Virginia. The standard of care is defined at §8.01-581.20 of the Code: "the standard of care by which the acts or omissions are to be judged shall be that degree of skill and diligence practiced by a reasonably prudent practitioner in the field of practice or specialty in this Commonwealth." However, this definition addresses practitioners, not organizations, such as HMOs.

Additionally, it would follow that if the State Health Commissioner is responsible for certifying that an HMO is unable to fulfill its obligations to furnish quality health care services, he should likewise be responsible for certifying that an HMO is able to furnish quality health care services. This is consistent with the requirement that the Health Commissioner examine the quality of health care services of any HMO licensed in Virginia. Again, there are no regulations to affect the development of standards by which to evaluate quality and no regulations to enforce noncompliance.

Neither the statutes nor the regulations contain explicit requirements for an HMO's quality assurance plan, structure, or functions. The only requirements for quality *per se* are that HMOs seeking licensure include a description of the procedures and programs they have adopted to assess the quality of health services provided and to assure availability and accessibility of adequate personnel and facilities.

Under the interim MOA between the BOI and the VDH, VDH participates with BOI in both initial licensure and market conduct examinations of HMOs. VDH examines the HMO's plan for QA and, during market conduct examinations, the degree to which the HMO has executed the plan. However, there is no statutory or regulatory requirement that HMOs comply with their QA plan and no provision for enforcement, nor are there standards for an adequate quality plan. Consequently, current law gives the HMOs broad discretion with regard to the content and execution of their quality programs.

B. Statutes and Regulations Addressing the "Consensus" Components of Quality: Chapters 43 and 34 of Title 38.2

The analysis of existing laws and regulations is done in the context of the components of quality to describe the dimensions of healthcare quality. (Appendix I). This discussion addresses the inadequacy of some of the current laws to provide minimum requirements to protect consumers. The analysis also summarizes the research undertaken by the University of Virginia, DHES. DHES surveyed managed care grievance and QA plans using questionnaires reviewed by the HB 2785 Study Group.

1. Complaint Resolution and Consumer Satisfaction

a. Problems in Current Laws

Since VDH began investigating quality complaints brought by consumers about their HMOs, timely cooperation in obtaining enrollee information to conduct the investigation varies among them. Without specific regulatory authority, current law provides VDH with an inadequate basis to determine whether a complaint about quality has merit or to enforce compliance with findings of the investigations. Since HB 2785 explicitly requires the VDH to "receive and respond to" complaints concerning quality of care, this directive requires standards upon which an examination of quality can be founded.

The regulations governing HMO complaint systems mandate that complaints be resolved in a "reasonable" amount of time, not to exceed 180 days. This time frame appears to be excessive.

HMOs are the only managed care entities required by law to have a system for complaint resolution, although all entities performing UR are bound by the mandates of Chapter 54 of Title 38.2 and all insurers are required to keep records of written complaints for a period of three years.

Although commercial plans are principally the purview of this study, it is useful to note the differences between the laws affecting definitions of key concepts for commercial plans and the DMAS' Medallion II contractors. Statutes for commercial plans define "complaint", and statutes for DMAS define "grievance" and "appeal." They do not define "complaint."

b. Research by the University of Virginia Department of Health Evaluation Sciences (DHES)

The grievance plans studied indicate that there is great variability in content among managed care companies, particularly with regard to the appeals process and the levels of appeal. There are also a variety of definitions of "complaint," "grievance," and "appeal." Most of the plans had no member information about the help available from the BOI Consumer Services Section.

c. Focus Groups

Participants in a provider and a consumer focus group expressed concern about complaint and grievance procedures. Several statements were made articulating the need for assistance in "navigating the system." Consumers and providers expressed the feeling that the process for filing a formal complaint with an HMO was complicated and confusing.

2. Access, Availability and Continuity

a. Problems in Current Laws

HMOs must submit for licensure a list of their contracted providers and must update the list quarterly. This allows the Bureau to monitor the number of providers and provider turnover. However, the only standards for access are found at 14VAC §5-210-90.A. and are vague, requirements, for example, that the HMO "maintain adequate arrangements to assure both availability and accessibility of adequate personnel and facilities . . . . " Other access standards include "reasonable" hours of operation and after-hours emergency care; "reasonable proximity to enrollees within the service areas so as not to result in unreasonable barriers to accessibility"; "sufficient personnel" to "reasonably" assure that all services will be accessible; "adequate arrangements to provide inpatient hospital services"; and the availability of "the services of specialists." "Reasonable," "unreasonable," "adequate," "sufficient" etc. is not defined.

The statutes addressing access to obstetricians and gynecologists (*Code,*§38.2-3407.11) and maternity length of stay *(Code*,§ 38.2-3414.1) are typical of laws passed in many states in response to public concerns that HMOs were too restrictive with certain types of services. However, this is a piecemeal approach to ensuring appropriate access to services and does not address many other services for which access is critical.

b. DHES Research

The QA plans of the HMOs surveyed appeared to emphasize accessibility of PCPs and appointment availability. A number of the HMOs mentioned specific PCP/member ratios and several reported standards addressing geographic accessibility. However, most of the ratios were expressed as the minimum number of patients a PCP had to accept rather than as a maximum limit acceptable to ensure access and appropriate time with the patient. The other managed care plans did not demonstrate a comparable emphasis on accessibility; this is likely a reflection of the fact that consumers in other forms of managed care have fewer restrictions on access to providers than consumers in HMOs.

c. Focus Groups

Participants in both consumer and provider focus groups raised concerns surrounding access to care. Concerns about access included access to services when the MCO denies authorization; availability of specialty providers; availability of appointments; waiting time to see a provider; and delay in services due to delays in approval. Access to particular drugs was also mentioned in the context where managed care companies use mandatory, rather than advisory, formularies. The study, however, did not examine these perceived problems to assess whether they are valid, and if so, the extent to which they are prevalent. Addressing these questions is regulatory in nature, and goes beyond the scope of this study. However, separating meritorious complaints from perceptions is difficult without adequate laws and regulations against which to make such assessments.

d. Complaints Under Investigation at VDH

VDH received 84 complaints concerning quality of care in HMOs in the period between December 1996 and October 1997. Fifteen of the issues presented to VDH concern access to care. The number of complaints represents a small percentage of total HMO enrollment in Virginia (.064 per 1000 enrollees). Yet, apart from the prevalence of the complaints, VDH is now required to respond to these, and future complaints -- whether from HMOs or other managed care plans. Discharging this mandate is problematic under current law without adequate quality of care requirements.

3. Prevention

a. Problem in Current Laws

The clearest and most comprehensive requirement for preventive health care services is found in the regulation setting forth the requirements for Essential Benefit Plans(14 VAC §5-234-50). Preventive care for children is required to be consistent with the current recommendations of the American Academy of Pediatrics; for adults, consistent with the recommendations of the American Academy of Family Physicians. However, this requirement is only for small group employers who choose the Essential Benefit Plan. Research by the BOI indicates that few small group employers are purchasing this plan for their employees.

Large group insurers are mandated to provide Pap tests, mammograms, and child health supervision services for preventive care. HMOs are required to provide "basic health services" defined to include preventive health services. The accompanying regulation at 14 VAC §5-210-90.B defines preventive services as "services provided with the goal of protection against and early detection and minimization of the ill effects and causes of disease or disability . . . ." Individual insurance policies have no mandated preventive health services.

By law, HMOs have the most stringent preventive health requirements. However, the regulation is very broad and it is unclear whether medical necessity criteria could conflict with the definition of "preventive" in the regulation.

b. DHES Research

The QA plans and interviews with HMOs demonstrated that the companies are stressing prevention for both healthy individuals and those with certain chronic conditions such as asthma and diabetes. Most of the companies surveyed are working on data collection for HEDIS measures and have developed preventive care standards with input from providers.

4. Credentialing

a. Problems in Current Laws

The Commonwealth's authority for licensure and professional qualifications of individual practitioners rests with the DHP. For the purposes of this analysis, credentialing is addressed with regard to the examination of professional qualifications performed by MCOs and the oversight of this process by the BOI, and through the MOA with the Department of Health.

There are no statutes or regulations requiring managed care entities to examine the credentials of their providers beyond state licensure. State licensure, however, only requires practitioners to adhere to minimum standards of competence. MCOs generally maintain that the stringent qualifications for a large proportion of their practitioners is a hallmark of quality. Under current law, it would appear that state regulatory agencies have insufficient basis to examine the credentials of providers or the credentialing system of the MCO other than to ensure that licensure verification occurs.

Much of the quality of health care rests with the individual practitioner. Consumers typically are not well informed concerning quality indicators for providers such as board certification and continuing education. However, the current regulatory guidance for standards for managed care provider credentialing does not permit the state any authority other than to assure minimal qualifications for individual providers through licensure by DHP. In particular, it is doubtful whether state oversight laws form a sufficient basis to verify the self-reported credentials of network practitioners, to determine whether an MCO's credentialing process is adequate, and to sanction the MCO for non-compliance with its own credentialing criteria.

b. DHES Research

DHES found that credentialing of providers was a prominent feature of the quality improvement plans examined and that managed care companies are committing significant resources to credentialing.

5. Consumer/Provider Education and Awareness

a. Problems in Current Laws

With respect to consumer awareness, the disclosure requirements in Chapter 54 of Title 38.2, which apply to all health insurers, are confusing. The statute at §38.2-5402 (F) requires that MCOs notify covered persons of the "review process." Without a regulation clarifying this section, it cannot be determined what exactly is meant by the "review process." Some members of the Study Group disagree as to whether it includes the appeals process.

As stated elsewhere in this study report, the appeals process in Chapter 54 is perceived by VDH as the most important quality of care protection provided by law. This protection is weakened by the confusing language in the statute and the lack of implementing regulations.

b. DHES Research

All HMO plans surveyed measure consumer satisfaction, often contracting with an outside vendor or using the HEDIS member satisfaction survey.

The consumer awareness survey for which DHES contracted with SIR surveyed a sample of 1,009 Virginia health insurance consumers. The results indicated the following about their experience with health insurance coverage, their awareness of grievance procedures, or both (Appendix G):

One third of Virginia health insurance consumers reported that they had called their health insurance company requesting information. Of that third, 20% reported having a difficult time getting answers.

One third of insured Virginians filing written complaints or grievances reported not knowing whether their insurer had a formal procedure for registering a complaint or filing a grievance.

One half of the respondents who have made verbal complaints had difficulty getting the complaint resolved.

Twelve percent of those surveyed said they had wanted to contact their health insurer with a complaint, but decided not to.

Four percent of Virginia health insurance consumers surveyed had filed a written complaint or grievance with their health insurance company; one third of these say they were never given a written copy of the grievance procedures. Another third who file a grievance said they found the insurer's procedures difficult to understand.

Nearly half of the respondents reported that they did not know to whom they would turn if they had a written grievance and found their health insurer uncooperative.

A significant majority (75%) believe that their households do not seek medical services often.

Two-thirds of the respondents are not aware of any procedure to file a complaint against a doctor, pharmacist, or other healthcare provider.

c. Focus Groups

In both the provider and the consumer focus groups the need for consumer and provider education was frequently articulated. Education concerning grievance systems and appeals was emphasized but consensus was apparent on the need for education on broader managed care issues. Although several participants spoke of the need for an ombudsman, there was also consensus that responsibility for education and assistance resides with all the players: employers, consultants, advocacy and professional groups, providers, consumers, and state agencies.

d. Ombudsman Programs in Other States

Currently, there are no state-funded managed care ombudsman programs in the United States. Florida has a voluntary program that is authorized, but not funded, by the state. California has a managed care ombudsman that is funded by three private health foundations: the Henry J. Kaiser Family Foundation, the Sierra Health Foundation, and the California Wellness Foundation. Funding for the program is $4 million for four years. The ombudsman will answer consumer questions and handle specific managed care complaints.

C. Chapter 54 of Title 38.2 of the *Code of Virginia* (Chapter 54)-- Utilization Review Requirements and Appeals

A weakness in the fee-for-service delivery system is that incentives to provide unnecessary services that have been in certain instances counterproductive to quality of care.[8] Utilization management involves setting guidelines for appropriate, cost effective, quality health care services. The UR appeals process in Chapter 54, including an expedited review when necessary, provides a means by which the patient's provider may challenge a managed care organizations' UR decisions. Sound criteria to determine whether a patient's treatment option is necessary combined with effective appeals to allow an orderly process for experts to reconcile differences in medical opinion provide the enrollee protection against unwarranted denial of medical services.

These protections are enhanced with state oversight to determine if the UR criteria are sound and whether the appeals process is functioning effectively. Unfortunately, it is difficult to reach any definitive judgment about the effectiveness of Chapter 54 because it was only enacted July 1, 1995. However, it is important to assess whether the oversight mechanisms are adequate to ensure that the law will perform as it is intended.

1. Problems in Current Laws

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[8]Peter Franks, M.D., Carolyn M. Clancy, M.D., "Gatekeeping Revisited -- Protecting Patients from Overtreatment" *Journal of the American Medical Association* (August 6, 1992), p. 424ff.

Chapter 54 incorporates the only protections specific to medical necessity determinations and appeals and safeguards the medical interests of Virginians enrolled in all types of managed care plans, not just those enrolled in HMOs. These provisions also constitute an effective mechanism through which providers can advocate for the medical needs of their patients. However, the statute does not provide sufficient systems-level protection for consumers. Additionally, there is no regulatory guidance or oversight responsibility for assuring compliance with the statute's requirements.

Throughout Chapter 54, consumer protections are constrained by the restrictions placed on BOI's oversight authority stating that: "the [State Corporation] Commission shall have no jurisdiction to adjudicate controversies arising out of this section." This restriction is appended to several key sections that address the UM system and process required of MCOs. These restrictions were put into the text because of the BOI's recognition of their lack of expertise in evaluating the adequacy of clinical criteria for medical decision-making. For example, §38.2-5402, which stipulates standards and criteria for UR entities, and §5403, which requires a UR plan, both end with qualifying statements to the effect that the Commission has the right to determine that the insurance entity has complied with requirements for standards and plans, but the Commission has no jurisdiction to assess the *appropriateness* of these standards and criteria. Moreover, this restriction also appears following the sections requiring accessibility of UR staff (§38.2-5404) and records of UR appeals (§38.2-5409). Considered as a whole, the restrictions limit the Commonwealth's ability to provide minimum systems-level protections addressing medical necessity decisions.

There are no regulations written for Chapter 54 that would clarify and explain its provisions. It is unclear in the statute as to what the role of the consumer should be in the review process regarding UR appeals and how the processes in Chapter 54 should be integrated with the grievance procedures provided in Chapter 43 of Title 38.2. For instance, the statute requires that providers be given notice of the MCO's initial decision to deny a benefit and notice of the right to seek a reconsideration of the decision (§38.2-5406 and §38.2-5407). No mention is made of enrollees as recipients of the notice in these sections. In addition, MCOs are required to give providers the UR standards and criteria and the list of physician advisors, but there is no mention of covered persons in this section either (§ 38.2-5402). The enrollee is not provided for in the appeals process until the last level of appeal, the appeal of a final adverse determination.

The requirements for the peer reviewer (§38.2-5408) are open to interpretation. Although the statute stipulates that the peer reviewer shall not be an employee of the MCO, one HMO stated that its peer reviewers were employed by the medical group which has an exclusive contract with them. Doctors in this medical group have no patients except those that are insured by this HMO. The HMO maintains that it is in compliance with the statute.

> Finally, with regard to HMOs, there is confusion concerning how the Chapter 54 appeals process intersects, if at all, with the grievance process mandated in Chapter 43 of Title 38.2. The two processes are very different (Appendix H, p. 21).
>
> The statute makes no provisions for enforcement or compliance. For example, there are no provisions for assessing the adequacy of the medical necessity criteria (§38.2-5402) or the UR plans used by MCOs (§38.2-5403.) Additionally, the statute makes no provision for appropriate sanctions based on the scope and severity of noncompliance.

In the past, BOI has been limited in its ability to resolve complaints against an MCO when the issue in dispute was the medical necessity for a covered service. Although BOI has attempted to advocate on behalf of the consumer, sometimes with success, when it became clear through the complaint handling process that the issue involved a difference in medical opinion between the managed care plan and the provider of medical care, BOI had to advise the complainant that it was unable to assist them further. Thus, while the BOI has the statutory authority to handle complaints, it lacks the medical expertise to determine appropriateness of care. On the other hand, VDH has the clinical expertise to evaluate the health plans' systems for determining medical necessity criteria and their appropriateness. The MOA provides a limited basis to review HMO UR procedures and requirements as they pertain to HMOs, but requirements for adequacy and appropriateness of UR criteria and enforcement of noncompliance with medical necessity criteria are deficient. In addition, a regulation clarifying and explaining the provisions of Chapter 54 could ensure that the protections intended to be provided by these statutes are understood by all.

2. DHES Research

> DHES conducted a survey of 31 HMOs and 200 other health insurers to determine the number of times consumers had appealed UR decisions in the last year, and to ascertain other information concerning the provisions of Chapter 54. Fourteen HMOs and 106 other health insurers responded. Forty-nine of the companies responded that they did not believe that the provisions of Chapter 54 were applicable to their organizations.
>
> The survey found that 12 HMOs had received reconsideration requests (first level appeal); the number for each HMO ranged from 12 to 482. For the other insurers, 8 had received reconsideration requests with the number for each ranging from 2 to 73. Eleven HMOs had conducted appeals of adverse decisions (final level appeal), and the numbers ranged from one to 781 for each HMO. Seven of the other insurers had conducted appeals, with the number for each ranging from one to 37. While the numbers of appeals should be considered with respect to enrollment in the plan, the confidentiality of the survey does not permit disclosure of enrollment numbers. Nonetheless, these presumably high numbers of appeals for some HMOs underscore the importance of quality protection for consumers who may be denied medical care by their insurer.

The examination of the grievance plans for HMOs and other insurers indicated that some of the plans contain procedures for Chapter 54 appeals that appear to be different than the requirements of the statute, particularly with respect to response times. None of the grievance plans contained any specific reference to Chapter 54. The research appears to indicate that MCOs frequently use internally developed medical necessity criteria rather than nationally accepted criteria such as Milliman and Robertson or InterQual.

3. Complaints Under Investigation by VDH

Of the 84 quality of care complaints received by VDH in a nine-month period, 52 (62%) of the issues presented to VDH concerned HMO UR decisions. (See also the above discussion of Complaints Under Investigation by VDH on p. 28.)

4. Focus Groups

Issues of medical necessity and managed care UR decisions dominated the discussion of the provider and consumer focus groups and emerged as the issue of most concern to both groups. Both providers and consumers related personal stories and anecdotes that would appear to indicate that serious errors occurred when the managed care entity denied or delayed authorization for treatment. Without independent examination and confirmation of the particular factual details involved, it is not possible to establish the accuracy of these accounts.

Providers focused on the fact that a service is only covered if it is deemed medically necessary and that managed care entities define medical necessity in their sole discretion. A representative from the Virginia Dental Association offered as an example the denial of an authorization for reconstructive oral surgery to enable a patient to chew food; the managed care entity allegedly said that it was not medically necessary because the patient was able to maintain weight on a liquid diet. Concern was expressed about the apparent lack of accountability of individuals making medical necessity determinations. Without independent examination and confirmation of the particular factual details involved, it is not possible to establish the accuracy of these accounts.

Providers expressed confusion about the appeals process and concern about the amount of uncompensated time required to appeal an MCO's medical necessity decision. One provider reported being told by an MCO that a denial of a request for durable medical equipment was not appealable under Chapter 54 and the question was raised as to whether drug formularies could be challenged under the statute. A number of providers indicated that they did not think that consumers knew of their grievance and appeal rights and that when they did try to grieve a decision they felt overwhelmed and confused by the process involved. Chapter 54 was cited as being confusing because there were no specifics addressing responsibility for implementation.

Participants in the Consumer Focus Group expressed concerns that the grievance process was confusing and that consumers needed assistance in "navigating" the system. It was not just the HMO's grievance procedures that were confusing; the assistance offered by state agencies was also characterized by one consumer as confusing. A representative from a consumer advocacy group made the point that individuals need to know the appeals process when their managed care plan denies authorization for a service and that they need a written notice of denial that includes information on the appeals process.

In the HMO Focus Group, there were several questions addressing UR appeals and Chapter 54. Three of the HMOs responded to the question concerning their use of Chapter 54; all three reported that the provisions for appeals in Chapter 54 were seldom used. The HMOs agreed that the determination of medical necessity was within the purview of the HMO.

5. UR Appeals Processes in Other States

In 18 states, the Department of Health monitors various aspects of the utilization review processes. Virginia's law is one of the more recent statutes providing appeals protections for managed care denials of care. Nine states have implemented or are in the process of implementing third party review of MCO UR decisions that is external, impartial, and independent of the health plan.

VDH reviewed the UR appeals laws in Connecticut, New Jersey, and Rhode Island (Appendix M, page 7) and compared them to Chapter 54. All these laws are directed at denial of treatment and require review by persons not involved in prior review of the case. Where the three states cited provide for impartial and independent review *after* the enrollee has exhausted the managed care organization's internal appeals process, Virginia law provides for impartial and independent review *within* the plan's internal appeals process: the peer reviewer is required to have not participated in any previous review of the case at issue and cannot be employed by or a director of the organization.

Connecticut, New Jersey and Rhode Island use independent utilization review organizations or peer review organizations. Virginia law requires the MCO to have physician advisors representing major areas of specialty that the MCO can use as needed for utilization review.

As Chapter 54 currently provides for impartial and independent review of appeals, the role of the state is to ensure that these provisions are observed by the managed care organizations.

D. Provider Concerns

HB 2785 directs the State Health Commissioner to "consider whether changes in existing law or regulations are warranted with respect to complaints by providers. . . ." The perception persists among providers that their concerns are not addressed by current laws. Among the most

commonly cited concerns are conflicts of interests built into the reimbursement system; denials of services that the providers believe are medically necessary; and fear of retaliation by the MCO if the provider challenges its decisions. However, it appears that many of the key concerns that providers raise about quality have been addressed in recent legislation. Several protections for providers are included in §38.2-3407.10 of the *Code of Virginia* , including provisions for disclosure of network development by a managed care entity, and the terms for inclusion in the network; prohibition of "gag orders"; and prohibition of contract provisions waiving the provider's right to seek legal redress or requiring a provider to indemnify the MCO for its negligence. The previous discussion on Chapter 54 concerning UR and appeals is another example of a recent law addressing the attending provider's concerns about their patient's medical needs. Furthermore, other concerns are being examined by private accreditation bodies, or could be addressed with improvements in the current oversight mechanisms.

1. Conflict of Interests

Two aspects of managed care may act to create ethical conflicts for providers. One involves reimbursement. Capitation or risk-assumption on the part of the provider creates an incentive to do too little for the patient, and some payment methodologies that include bonuses for avoidance of hospitalization and specialty care may exacerbate that tendency. Although §38.2-3407.10 of the *Code* addressed this concern by requiring disclosure of all reimbursement methodologies, this provision does not affect the behavior of individual practitioners. Practitioners are bound by professional ethics. Those practitioners tempted to provide substandard care in exchange for profit do so at considerable risk because of the effective quality mechanisms provided by the DHP. Individuals who believe they have received poor care can bring their concerns to DHP, and both BOI and the Health Department refer quality problems to DHP whenever there is indication that an individual practitioner did not observe the standard of care (Appendix H, pp. 31-40).

The second conflict of interests is created when providers are bound by a limited network or formulary; when they must refer a patient to a network provider rather than one who can better help the patient, or when they must prescribe a drug less efficacious than an off-formulary drug. These are valid concerns, but currently there are few mechanisms in the private or public sector to address them. National accreditation organizations do not review formularies nor the complaints against network providers. Moreover, state insurance regulators do not have the clinical expertise to make these judgments. This concern highlights the importance of state oversight by an agency with expertise in health care, and explains why many states have adopted coordinated regulation of managed care by departments of health and insurance.

2. Denial of Care

It was clear from the Provider Focus Group convened by the HB 2785 Study Group that a pressing concern that providers have with managed care is the denial of services on the grounds that they are not medically necessary. While Chapter 54 of Title 38.2 provides an appeal process

for providers and requires review by a peer of the treating provider, many providers appear to be unfamiliar with the provisions of the statute.

There is currently no regulatory mechanism to address the perceptions of the medical community that medical necessity decisions by insurers are eroding the quality of care received by the public. Chapter 54 contains ten sections; seven sections include a declaration that the BOI has no jurisdiction to adjudicate disputes that may arise as a result of implementing the provisions of this statute. Four of these assertions affect the UR requirements, and three affect the UR appeals process. Under current law, the level of oversight extends to validating that MCOs have requirements and standards for UR; a UR plan; accessible utilization reviewers; procedures for emergencies, extension of services, safeguards for confidentiality of medical records; as well as requirements for the UR appeals process, including the collection of records on review procedures and decisions. No mention is made to the role of the State Health Commissioner in this Chapter. Without proper statutory authority conferring oversight duties upon the State Health Commissioner, it is uncertain how this concern can be addressed.

3. Fear of Termination

Providers perceive a threat to their livelihood if they challenge the decisions of an MCO with whom they have contracted. However, Chapter 54 (§38.2-5408 G) prohibits contract termination or penalties of any sort against a provider for advocating on behalf of a patient in a medical necessity dispute unless it can be demonstrated that the provider has established a pattern of bringing appeals that are without merit. This issue was also discussed during a focus group with the HMOs. Several HMO representatives responded that their plans had communicated to network providers that they welcomed attending physicians to advocate for the medical needs of their patient (Appendix K, pp. 21,22). Without judging the merit of this allegation, state enforcement of this provision will be difficult for any state agency. It is important to recognize that private accreditation organizations are seeking to address concerns such as these as they develop their standards.

4. Accreditation Standards Addressing Provider Concerns

Both NCQA and AAHCC/URAC have accreditation standards that actively incorporate input from practicing physicians and other providers in several areas of plan operations. NCQA promotes practitioner involvement in the development and implementation of quality improvement programs and in the development of practice standards and UR criteria. Health plans are also required to survey provider satisfaction with the UM process. NCQA has a standing Practicing Physician Advisory Council (PPAC), whose purpose is to examine physician concerns affecting quality. PPAC has been exploring ways to use the accreditation standards process to modify plan behavior with respect to many issues, including practitioner termination issues.

AAHCC/URAC requires the involvement of providers in network management on advisory boards, such as peer review, appeals, quality management, or other committees. URAC - which has now merged with AAHCC - was established largely to address provider concerns. Networks are required to have a "participating provider communication program" and to establish a provider dispute and appeals process for any disciplinary actions taken against providers.

In general, the directions of the private sector with respect to addressing provider issues pertaining to quality is encouraging. Having plans work together with providers with whom they must contract to be competitive may prove a more promising solution for certain provider issues than state regulations.

VIII. SHOULD ALL MANAGED CARE ENTITIES BE HELD ACCOUNTABLE FOR QUALITY OF CARE PROTECTIONS?

In the past two years, much of the legislation pertaining to quality has addressed all managed care plans rather than HMOs exclusively. The issue is whether provisions that currently apply to HMOs (e.g., such as requiring a complaint system or quality of care plan) should also be required of other forms of managed care. As noted in the Background, there are other managed care studies concurrently under way that are relevant to quality of care issues. The General Assembly has directed BOI to study the regulation of managed care plans. Specifically, HJR 611 directs BOI "to (I) identify the types of health insurance plans that should be considered as managed care plans; (ii) review the provisions of Chapter 43 of Title 38.2 and evaluate which provisions, if any, should apply to other forms of managed care health insurance plans . . . ; and (iii) identify any other appropriate provisions of the *Code of Virginia* or regulations promulgated by BOI that should apply to the types of health insurance plans identified as managed care plans." BOI is the most appropriate body to define "managed care health insurance plans" and determine which laws are applicable to these entities. Consequently, this study defers to the outcome of BOI's analysis on these issues.

With respect to whether the HMOs and other forms of managed care plans should be treated similarly under the *Code of Virginia*, it is crucial to recognize that the traditional regulatory distinctions have become blurred in this rapidly changing health care delivery business. The National Association of Insurance Commissioner's (NAIC) Risk-Bearing Entities Working Group concluded that the trend among state regulators is toward "pursuing initiatives to eliminate artificial distinctions that are irrelevant in today's marketplace." Thus, the Working Group's two findings present a reasonable basis for assessing whether it is justifiable to treat all managed care plans similarly under the *Code of Virginia*:

> All entities which assume health insurance risk must be subject to solvency and other appropriate consumer protection standards, irrespective of the name and form of the entity; and

> Any regulatory framework should foster a level playing field among risk-bearing entities that engage in similar insurance arrangements as opposed to a regulatory framework that favors the development or maintenance of any particular organizational form assuming insurance risk.

If the HJR 611 study determines that the statutes and regulations governing the quality of care in HMOs are applicable to other forms of managed care plans, then the policy interests of so-called "functional regulation" and "fair treatment" of entities bearing health insurance risk ("a level playing field") justify the desirability of applying these laws to other forms of managed care. In addition, the public health concerns for promoting safety, health, and welfare of Virginians bolsters the applications of these market and regulatory principles. From the public health perspective, the public's safety is potentially at risk in health plans that deny, reduce, or terminate services.

Another related issue is whether it is appropriate for the other forms of managed care plans to have procedures for QA, grievances and the like. For instance, in its simplest form, managed care may include pre-certification of hospital stays or UR to ensure services received by patients are medically necessary. As such, "managed care" processes exist in many different types of health insurance plans, including indemnity plans. More advanced forms of managed care, often referred to as PPOs and POS plans, not only require UR and medical necessity determinations, but also provide incentives for enrollees to receive care from network providers in order to obtain the highest level of the plan's benefits. Some PPOs and most POS plans also require an enrollee to select and use a PCP who provides primary care and coordinates access to other health care services. The most advanced form of managed care is provided by HMOs. Most HMOs require each enrollee to select a PCP, require use of network physicians (unless a POS option is included), and generally have smaller specialty networks than plans referred to as PPOs and POSs.

National surveys suggest that quality of care mechanisms are prevalent in PPOs. For instance, a national survey (Gold, Hurley, et.al. , 1995; Appendix Q) of 138 managed care plans in 20 metropolitan areas, including Virginia, found the following quality of care procedures used by PPOs:

> Sixty-two percent had a QA or Quality Improvement program and active patient grievance procedures;
>
> Thirty-one percent used quality monitoring and focused studies of specific conditions, and targeted quality of care improvement;
>
> Forty-five percent used physician profiling;
>
> Thirty-seven percent employed UR;

Only seven percent developed practice guidelines.

In April 1997, the Association of Managed Healthcare Organizations (AMHO) conducted a survey of its members, principally PPOs and other managed care plans. The survey indicated that most of its membership have written, formal QA plans (more than 80 percent); QA committees (more than 90 percent); quality indicators for performance goals (86 percent); and patient appeals/grievance process (93 percent). Many conduct routine patient satisfaction surveys (70 percent). Nearly half use some form of outcome measures (43 percent); or monitor sentinel clinical events (45 percent), as well as profile physician performance on various quality indicators. In addition, the plans reported that nearly two-thirds routinely survey providers regarding access and other quality of care indicators, and nearly all plans responding offered a provider appeals/grievance process (Appendix Q).

Research by DHES on the quality of care procedures in non-HMO insurance organizations licensed in Virginia could not confirm or invalidate the general patterns above. This was due to the fact that some of the companies that said they had QA plans did not submit the plans.

If regulation of other forms of managed care is determined to be desirable, the appropriate standards for quality and grievance plans could be determined through the rule-making process.

IX. CONCLUSIONS

State laws cover many areas of quality appropriate to the state oversight system. However, the oversight system can be made to perform more effectively to protect consumers by addressing the weaknesses in systems-level safeguards.

The appropriate role of state regulatory agencies is to ensure systems-level protections provided by law. In 21 states outside of Virginia, the Department of Health is responsible for assuring compliance with state managed care quality standards. As the health care system in Virginia continues the transition to managed care, regulatory change is needed to keep pace with the changes in health care delivery and reimbursement. Two areas need attention. First, the State Health Commissioner and the Department of Health lack sufficient statutory authority and regulatory guidance for appropriate oversight of HMO quality. HB 2785 directs the Health Commissioner to examine the quality of health services and complaint systems in HMOs, and to review and respond to complaints of enrollees in managed care plans. Neither current statutes nor the MOA between the BOI and the VDH provide the authority to appropriately execute this directive.

A second opportunity to improve the state oversight system involves the implementation and administration of Chapter 54 of Title 38.2. This chapter provides the most comprehensive protections for managed care enrollees who are denied coverage for health care services deemed by their health plan not to be medically necessary. However, the state can do more to assure this important consumer protection. The provisions of Chapter 54 are not well known or understood

by providers and consumers. Limitations on systems-level protections are written into the statutes and the absence of regulations for this chapter further limits state oversight of compliance and enforcement. The subject of the legislation, medical necessity determinations and appeals, is beyond the scope of the traditional expertise of the BOI. VDH has the expertise to determine the adequacy of and adherence to UR criteria, important provisions in the statute, but unlike other states, the Virginia statute provides no role for the Health Commissioner.

These problems may provide some insight into the worries that consumers have about the services they receive in managed care plans and why some believe individual protections such as an ombudsman and independent external appeals process are appropriate solutions. However, the state does assist individual consumers in resolving their disputes. For example, one role of the Consumer Services Section of the BOI is to educate consumers and, in some instances, to advocate on their behalf with their insurance companies. In addition, VDH has the expertise to assume additional educational responsibilities in assisting both enrollees and providers with internal HMO grievance and appeals processes. To extend the ombudsman role to include adjudication of conflicts would require the state to assume the roles of both mediator and regulator, an inherent conflict.

Moreover, a new external appeals process protection for denial of treatment may not be needed at this time if Chapter 54 is administered by an agency with clinical expertise, and if adequate regulatory guidance is available to preserve the independence and impartiality of these critical medical decisions. To achieve this policy objective requires that agencies responsible for oversight of quality have proper expertise.

Private sector accreditation of managed care has made significant contributions to quality improvement that complement, but should not supplant, state oversight.

Private sector efforts by HMOs and national accreditation organizations continue to provide a focus on improvement of health care and measurement of quality. State oversight of HMOs will be accomplished most efficiently in collaboration with private-sector quality initiatives. Modifying plan behavior through a private accreditation process is an effective avenue for quality improvement that offers several advantages to State policy makers.

Consumers and providers need more education about managed care.

There is a need for more and better education about managed care issues for consumers and providers as demonstrated in the focused round table discussions and the consumer awareness survey. Consensus was evident regarding the parties responsible for better education and awareness: employers, professional and advocacy groups, managed care organizations, consumers, providers, and state agencies. In particular, consumers need to be better informed about the current protections afforded them through the laws, their health plans, and through the BOI and VDH.

HMOs have significantly more legal requirements addressing functions performed by other licensed managed care organizations.

Statutes and regulations addressing quality of care in HMOs expressly address particular functions, such as quality assurance plans, complaint procedures and provider networks. The lack of similar requirements for other managed care organizations performing the same functions creates a gap in consumer protection and contributes to a competitive disadvantage for HMOs.

Current VDH resources are insufficient to carry out legislative mandates for quality oversight.

Although it is difficult to estimate the necessary resources, if it is desirable forVDH to provide oversight of all forms of managed care, additional staff at VDH are needed to assist with complaint investigation and to conduct examinations, and additional funding will be needed for expenses attendant to these functions. The resources needed will depend on the degree to which other forms of managed care are brought into the scope of VDH's regulatory purview.

Federal laws and oversight complicate state oversight of managed care. However, opportunities for oversight partnerships maybe possible.

Health care benefits provided through Medicare, Medicaid, CHAMPUS, federally-funded plans or ERISA self-funded plans are exempt from much or all of state oversight requirements governing quality. Nevertheless, Virginia can signal its interest to work in partnership with the federal government and large employers to ensure quality protections in employer-funded health plans.

X. WHAT IS THE *APPROPRIATE* ROLE OF THE COMMONWEALTH IN MONITORING AND IMPROVING QUALITY OF CARE IN MANAGED CARE ORGANIZATIONS?

HB 2785 requests the State Health Commissioner to make recommendations on whether additional changes are needed in the Commonwealth's oversight responsibilities for quality of care in commercial MCOs. This section presents options for changes necessary for the state to have effective minimum requirements to assure quality of care in managed care plans. These options are not intended to represent all possible options, but rather the most viable or frequently advocated options.

A. POLICY OPTIONS

Systems-level Safeguards Can Be Improved

Option #1a: Amend the *Code of Virginia* at §32.1 to grant the State Health Commissioner authority to certify the adequacy of the HMOs' quality and grievance plans and to ensure compliance. The statute would also direct the BOH to promulgate a regulation defining the certification process that would:

direct VDH to certify that the health plans meet minimum standards for adequate quality and grievance systems as defined in the regulation;

allow VDH to verify implementation and execution of the quality and grievance systems and would permit the health plans reasonable latitude for innovation;

direct the BOH to determine the frequency and expectations for onsite surveys of the health plans, and make provisions for deemed status for accredited health plans;

require that the BOH determine a schedule of reasonable sanctions based on scope and severity of noncompliance, and an appropriate mechanism for financing examinations.

require that VDH report its HMO certifications of quality and grievance programs to BOI annually.

Option #1b
(alternative to #1a): Request legislation to codify the existing MOA between VDH and BOI with respect to the shared responsibility for oversight of HMOs, and to expand its authority to include all MCOs as defined by the BOI under HJR 611.

Option #1c
(alternative to #1c): Make no changes to the current oversight authorities.

Option #2: Request legislation defining key terms such as "inquiry," "complaint," and "grievance," etc.; and requiring a standard classification scheme for quality complaints to be used by MCOs and appropriate state agencies.

Option #3: Request that the statutory provision at §54.1-2906 be amended to require that MCOs report provider disciplinary actions to DHP.

Option #4a: Request legislation to transfer Chapter 54 from Title 38.2 of the *Code* to Title 32.1 and confer authority for administering and enforcing its

provisions to VDH through the certification process. The legislation additionally would:

Authorize regulations for VDH to discharge oversight responsibility. The regulatory authority would only extend to systems-level compliance with Chapter 54 of Title 38.2, including, but not limited to, assessment of UR plans and criteria; UR appeals process, including disclosure of the review process to covered persons; and sanctions based on the scope and severity of noncompliance.

Clarify requirements for the submission and collection of appeals' data (§38.2-5409)

Amend Chapter 54 to include consumers in all levels of appeal

Option #4b
(alternative to #4a): Make no changes to Chapter 54 of Title 38.2 at this time.

Option #5: Request budget authority to support the HB 2785 mandate that VDH receive and respond to individual enrollee complaints by conducting system-level reviews of managed care plans.

Option #6: Request legislation requiring an independent and external appeals process to resolve questions of medical necessity that have not been satisfactorily resolved through the commercial MCO's internal appeals process.

Option #7: Seek legislation to establish and fund an ombudsman for health insurance issues to educate consumers about their rights and responsibilities, mediate disputes between insurers and consumers, and advocate for mutually satisfactory resolutions. The ombudsman would most appropriately reside with an independent private contractor.

Consumers and Providers Need More Education about Managed Care

Option #8: Amend the *Code* at Chapter 54 of Title 38.2 to require disclosure of the UR appeals process at the time that care is denied and/or in the Evidence of Coverage and other communications from the health plan.

Option #9: Create a public/private partnership with VDH as the facilitator to organize educational strategies to help enrollees, purchasers, and providers become better informed about their rights and responsibilities regarding complaints, grievances,

and appeals. Participating organizations could include the Virginia Association of HMOs, the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, consumer advocacy groups, businesses, other organizations and appropriate state agencies. (*No legislation is required for this option.*)

Option #10: Currently there is no standardized coding to indicate payor health plan type (e.g., HMO, PPO, POS, etc.) VDH's health data reporting contractor is committed to a strategic plan to develop hospital inpatient data with health plan identifiers. With this information, VDH or its contractor can assess and report information by specific plan type.

Option #11: VDH or its contractor will work with managed care plans to collect audited HEDIS data submitted voluntarily. The State Health Commissioner will encourage health plan participation in HEDIS reporting and will publish a list of those managed care plans that voluntarily participate with VDH's health data reporting contractor.

HMOs Functions Are More Regulated than the Same Functions Undertaken by Other Managed Care Organizations

Option #12: Support the underlying policy for options presented by BOI in their study pursuant to HJR 611that codify provisions in Chapter 43 of Title 38.2 which are applicable to other forms of managed care health insurance plans.

Option #13: Amend Title 32.1 of the *Code of Virginia* to increase the size of the State BOH to twelve members, with the additional appointee to be a representative of a managed care plan.

Possible Opportunities for Federal/State Collaboration Involving Self-funded Plans

Option #14: BOI should notify the Assistant Secretary of Labor, Pensions & Welfare Benefits Administration, U.S. DOL, about Virginia's interest in exploring a possible future role for BOI in resolving ERISA complaints on behalf of the citizens of this Commonwealth.

Option #15: Track ERISA-protected quality of care complaints through BOI with the assistance of other state agencies, such as DPT.

B. STATE HEALTH COMMISSIONER'S RECOMMENDATIONS

The following options are recommended to strengthen the existing laws and to provide for the least minimum requirements to ensure quality of care for all Virginians in licensed managed care plans:

1. Improve systems-level protections (Options 1a, 2, 3, 4a, and 5)

These options permit the certification by VDH of the adequacy of mandated quality assurance and grievance procedures; allow for sanctions for non-compliance; and strengthen protections for consumers. The changes recommended for Chapter 54 are necessary to ensure the important safeguards against arbitrary denials of care.

2. Facilitate managed care education for consumers and providers (Options 8,9,10, and 11)

Option 8 is recommended to ensure that consumers are aware of their legal right to appeal managed care denials of coverage. The other options do not require legislation and address a need for education that was clearly articulated over the course of this study.

3. Support BOI policy regarding regulation of managed care entities by function (Options 12 and 13)

Because the distinctions between HMOs and other managed care organizations have become increasingly blurred, it is appropriate to examine the functions that MCO's are performing and bring them under regulatory oversight where it is applicable.

4. Address managed care protections for Virginians in employer-funded plans (Options 14 and 15)

Many states have become concerned about the lack of protections for consumers in ERISA self-insured plans, and it is likely that Congress will address this issue. In the meantime, the recommended options are very easy to implement and are an important step toward quality health care for all Virginians.

C. OPTIONS NOT RECOMMENDED

1. Codify the MOA between the BOI and the VDH (Option 1b)

This option is not recommended because the MOA cannot provide for authority that BOI currently does not have and because it is not appropriate for BOI to enforce VDH's findings of HMO non-compliance with applicable statutes and regulations.

2. Independent External Appeals Mechanism (Option 6)

Chapter 54 of Title 38.2 has provisions similar to those in other states where an independent appeals mechanism has been implemented. If authority for oversight and regulations for Chapter 54 is transferred to VDH, and the statute's protections enforced, there should be no need for an external appeals mechanism at this time. Also, ERISA may pre-empt self-funded employer-sponsored plans from state requirements.

3. Ombudsman (Option 7)

The action is not necessary at this time. Many complaints are resolved through education. BOI provides assistance to consumers and VDH is proposing to assume increased enrollee educational responsibilities. Improvement of systems-level oversight of complaint and UR appeals systems can also improve the perfomance of the health plan. These approaches should be implemented first. Furthermore, functions of advocacy and mediation may pose conflicts of interest for state agencies that regulate managed care. Finally, this consumer protection would be costly.

4. Make no changes (Option 1c and 4b)

These options are unsupportable because the current mechanisms to ensure quality in managed care are not sufficient.